IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

NEWPORT NEWS DIVISION

SOLSYS MEDICAL, LLC
f/k/a and d/b/a Soluble Systems, LLC
11830 Canon Blvd, Suite A
Newport News, Virginia 23606,

Plaintiff,

- against -

ORGANOGENESIS, INC.
150 Dan Road
Canton, Massachusetts 02021

Serve on:
The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, Delaware 19801
(File no. 2061206),

Defendant.

CASE NO.:

COMPLAINT FOR FALSE ADVERTISING UNDER LANHAM ACT § 43(a), 15 U.S.C. § 1125(a), AND VIRGINIA CODE §§ 18.2-216, 59.1-68.3

Plaintiff Solsys Medical, LLC ("Solsys") for its Complaint against Organogenesis, Inc. ("Organogenesis"), alleges as follows:

PARTIES

1. Plaintiff Solsys is a limited liability company organized under the laws of Delaware with its principal place of business at 11830 Canon Boulevard, Suite A, Newport News, Virginia 23606.

2. On information and belief, Defendant Organogenesis is a corporation organized under the laws of Delaware with its principal place of business at 150 Dan Road, Canton Massachusetts 02021.

JURISDICTION AND VENUE

3. This action arises under 15 U.S.C. § 1125(a) and the statutory laws of the Commonwealth of Virginia. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question), 15 U.S.C. § 1121 (Lanham Act claims) and 28 U.S.C. § 1367 (supplemental jurisdiction over pendant state law claim).

4. Plaintiff is informed and believes, and on that basis alleges, that this Court has personal jurisdiction over Defendant because Defendant has extensive contacts with, and conducts business within, the Commonwealth of Virginia and this judicial district; Defendant has caused Apligraf® (a wound treatment device as described further below) to be inappropriately advertised, promoted, and sold in this judicial district; the causes of action asserted in this Complaint arise out of Defendant's contacts with this judicial district; and because Defendant has caused tortious injury to Plaintiff in this judicial district.

5. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because Defendant has caused Apligraf product to be inappropriately advertised, promoted, and sold in this judicial district; the causes of action asserted in this Complaint arise out of Defendant's contacts with this judicial district; and because Defendant has caused tortious injury to Plaintiff in this judicial district.

FACTUAL ALLEGATIONS

Introduction of Apligraf to The Market

6. Organogenesis markets, under the brand name of Apligraf, a medical device indicated for use as part of a treatment regimen for certain types of diabetic foot ulcers ("DFUs") and venous leg ulcers ("VLUs").

7. Apligraf is a viable, bi-layered, skin construct, containing Type I bovine collagen, extracted and purified from bovine tendons and viable allogeneic human fibroblast and keratinocyte cells isolated from human infant foreskin.

8. Upon information and belief, notice of FDA's approval to market Apligraf was issued on or about May 22, 1998.

9. In order to receive FDA medical device approval, Organogenesis submitted an application for premarket approval (PMA). According to the Summary of Safety and Effectiveness Data that is publicly-available on the FDA's website, the PMA included data from a 297 patient prospective randomized controlled study (the "Organogenesis Pivotal Trial") evaluating the safety and effectiveness of Apligraf and compression therapy in comparison to an active treatment concurrent control of zinc paste gauze and compression in VLUs of greater than one month duration that had not adequately responded to conventional ulcer therapy in patients with VLUs.

10. The primary study endpoints were 1) the incidence of 100% wound closure per unit time and 2) the overall incidence of 100% wound closure by 6 months. "Complete Wound Closure" was defined as "full epithelialization of the wound with the absence of drainage."

FDA's expert advisory panel concurred that the study's definition of wound closure was consistent with the definition of a "healed" ulcer.

11. The study met the first primary endpoint but not the second. The adjusted frequency of complete wound closure as a function of time at 24 weeks was 56.8% for Apligraf patients, versus 39.8% for patients receiving active control.

12. With respect to the second primary endpoint, however, FDA concluded that, while the incidence of wound closure by 6 months was numerically superior to the active control, the result was not statistically significant.

13. In patients treated with Apligraf, suspected infection was reported at more than twice the frequency (29.2%) than patients receiving active control (14.0%).

14. Based on the recommendation of its General and Plastic Surgery Devices panel, FDA approved Organogenesis' PMA for Apligraf.

Introduction of TheraSkin® to the Market

15. On or about October 2009, Solsys, under its former name of Soluble Systems, LLC, began to market a competing cellular and tissue based product for the treatment of slow-healing or chronic wounds including DFUs and VLUs under the brand name of TheraSkin.

16. TheraSkin is an FDA-regulated biologically active product, but unlike other biologically active products, TheraSkin comprises only cryopreserved human skin allograft. Unlike Apligraf, TheraSkin does not include animal-derived or human cultured cells or tissues.

17. TheraSkin also differs from other acellular products manufactured from human skin which are made exclusively of remaining collagen scaffold and do not contain the native growth factors of cytokines found in the cells of living skin tissues.

18. TheraSkin can be used to treat external wounds head to toe and has a fully developed extracellular matrix (ECM) with living cells and an "at ready" supply of human growth factors, cytokines and collagen to jumpstart the wound healing process.

19. Post-market studies of TheraSkin have demonstrated the product's safety and effectiveness in treating both DFUs and VLUs.

20. For example, a retrospective clinical study of 188 patients seen at the Inova Wound Center in Mount Vernon, Virginia found that approximately 60% of DFU and VLU wounds had closed by 12 weeks of treatment with TheraSkin, and roughly 75% of VLUs and DFUs had closed after 20 weeks of treatment with TheraSkin.

21. Consistent with Organogenesis's Pivotal Trial, the authors of the TheraSkin study defined wound "closure" as the complete epithelialization of the wound without drainage.

22. TheraSkin and Apligraf represent treatment alternatives that compete against each other for adoption and sales to providers, including hospitals, wound care clinics and physician office sites of service and their respective patients.

Organogenesis' Faulty Retrospective Study

23. In or about 2015, Organogenesis funded a retrospective study (the "Organogenesis Retrospective Study") that purported to compare the effectiveness of Apligraf against TheraSkin in the treatment of VLUs. Upon information and belief, the authors of the Organogenesis Retrospective Study were all paid by Organogenesis and include a current Organogenesis Board member, as well as current or former employees of Organogenesis and/or paid consultants of Organogenesis.

24. Organogenesis' Retrospective Study differed in a number of significant respects from Organogenesis' Pivotal Trial. Examples of these differences include the following:

a. As the name implies, rather than conduct a prospective randomized clinical trial on patients as was done in the Organogenesis Pivotal Trial, the authors of the Organogenesis Retrospective Study looked at a selected set of electronic medical records of patients that already were treated with either Apligraf or TheraSkin. These records were obtained from an electronic medical records database maintained by Net Health.

b. Organogenesis' Pivotal Trial compared, for purposes of determining safety and effectiveness, the use of Apligraf with compression against a control set of patients using zinc based gauze and compression. Organogenesis' Retrospective Study purports to establish the comparative effectiveness of Apligraf versus the use of TheraSkin, and it is unknown whether compression was applied to any of the patients.

c. Organogenesis' Pivotal Trial defined wound closure as the complete epithelialization of the wound without drainage, whereas Organogenesis' Retrospective Study defined wound closure as an ulcer achieving an area of less than or equal to .25cm^2.

d. Organogenesis' Pivotal Trial took into account relevant variables that could skew the outcomes of the results including underlying comorbidities of potential trial participants. Organogenesis' Retrospective Study made no effort to account for comorbidities of study participants that could skew the outcome of the results.

25. Upon information and belief, Organogenesis' Retrospective Study included numerous errors and omissions that call into question both the validity of the study's conclusions and the objectivity of its authors. These include glaring methodological errors and the omission of key information necessary to evaluate the validity of the authors' findings. For example:

a. According to the Baseline Wound Characteristics found at Table 2 of Organogenesis' Retrospective Study, the mean wound duration (i.e., the presence of the wound

before treatment) was almost 3 months longer for patients treated with TheraSkin than those patients treated with Apligraf, suggesting that those wounds were significantly worse that the wounds treated with Apligraf and would therefore be expected to heal more slowly.

b. The number of applications, the interval between applications, and the number of debridements are all very different from each other, all of which would impact the effectiveness and the cost of use, yet none of this is included in the analysis.

c. According to the Treatment Characteristics and the text of Organogenesis' Retrospective Study, "significantly" more patients using Apligraf required multiple applications indicating that a single application of TheraSkin was more effective.

f. The authors of Organogenesis' Retrospective Study conclude that a difference in time for healing would suggest that Apligraf would provide cost savings, despite the fact that a patient receiving multiple applications of Apligraf at a unit price of $1,295 (per 44 sq. cm. disk) would incur a cost of at least twice as much as a patient receiving only one application of a similarly sized and priced unit of TheraSkin.

26. Organogenesis' Retrospective Study also included statements that were not only false and misleading but also were disparaging to TheraSkin and unfairly cast doubt on the quality and intended use of ThereaSkin.

27. In particular, Organogenesis' Retrospective Study implies that only Apligraf is regulated by FDA, when in fact both products are subject to stringent FDA requirements that are tailored to their respective properties and methods of manufacture. Unlike TheraSkin, which is a minimally-manipulated human tissue-based product that is intended for homologous use, Apligraf is an extensively processed medical device that incorporates both human and non-human cellular and non-cellular components. As Apligraf is classified as a high-risk medical

device, the FDA imposes more restrictions on the sale and distribution of Apligraf in order to protect the public.

28. Organogenesis' Retrospective Study also falsely characterizes TheraSkin as a "wound covering" (in contrast to a wound treatment). In fact, pursuant to applicable FDA regulations, TheraSkin is intended to perform any "homologous use," i.e., any use that it would perform in its native state, including, in the case of human skin, wound healing.

29. Organogenesis' Retrospective Study also erroneously implies that the quality of TheraSkin will vary based on the differences in the donors from whom the tissue was derived, and that such variation will adversely affect TheraSkin's therapeutic capacity. In fact, there are strict screening criteria used to minimize variation between sources of the tissue used to manufacture TheraSkin, including procuring of tissue from specific areas of the body and excluding donors based on age or health conditions.

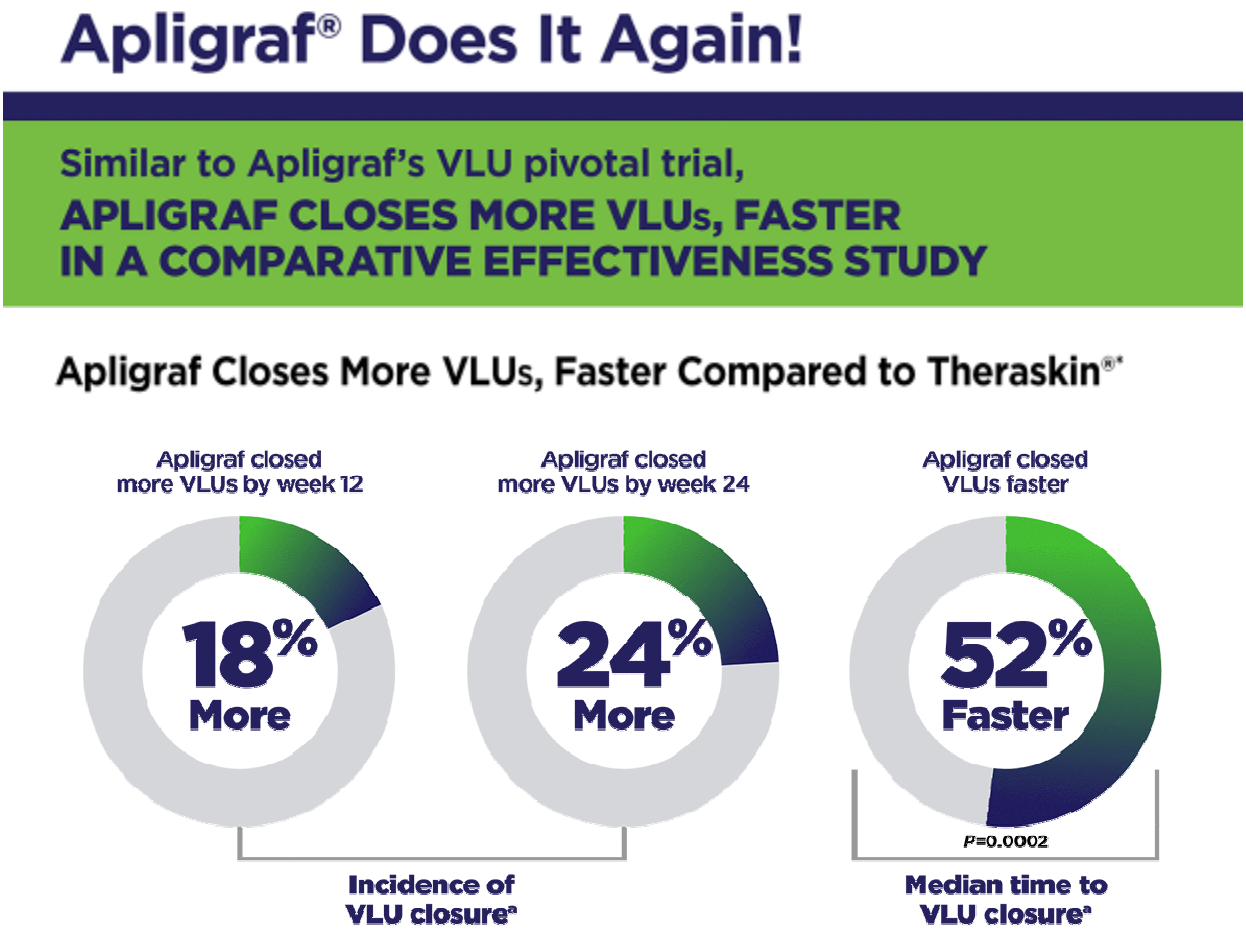
Organogenesis Falsely Advertises Alleged Comparative Superiority

30. Despite the fact that Organogenesis' Retrospective Study differs markedly from Organogenesis' Pivotal Trial, and that Organogenesis' Retrospective Study contains inconsistent, false and misleading statements, Organogenesis nevertheless created an advertisement ("Advertisement") and marketing campaign offering its own interpretation of the results of Organogenesis' Retrospective Study.

31. That Advertisement (attached as Exhibit 1, which includes and incorporates a linked copy of Organogenesis' Retrospective Study (also attached at Exhibit 1)), was widely disseminated via e-mail blasts to hospitals, wound care clinics, health care providers, and other customers for the purpose of influencing their purchasing decisions.

32. However, the Advertisement, like Organogenesis' Retrospective Study, contains false and misleading statements and omissions of fact that are material and that have deceived their targeted audience.

33. The Advertisement, sent out with the e-mail blast containing a subject line reading "How to Heal More VLUs, Faster", starts out as reproduced below:



34. However, the factual assertions that "Apligraf Does It Again!", and "Similar to Apligraf's VLU pivotal trial" are demonstrably false.

35. Organogenesis' Pivotal Trial and Organogenesis' Retrospective Study employed markedly different study designs, included different study endpoints, and achieved different outcomes. In particular, Organogenesis' Pivotal Trial was a randomized controlled trial (RCT), which is considered by FDA to be the "gold standard" for evaluating product safety and efficacy. By contrast, FDA historically has not accepted data from the retrospective review of patient data in making regulatory decisions and has expressed serious concerns about the myriad potential opportunities for bias in such studies that can affect the validity of the results.

36. By linking Organogenesis' Pivotal Trial with Organogenesis' Retrospective Study, Organogenesis is intentionally deceiving the consumer into believing that Organogenesis' Retrospective Study incorporated the same protocols, and received the same FDA stamp of approval when in fact Organogenesis' Retrospective Study did not get any FDA stamp of approval.

37. Significantly, Organogenesis' Pivotal Trial and Organogenesis' Retrospective Study employ different definitions of wound "closure."

38. Consistent with the generally accepted understanding of the key term "closure" among wound care experts in the field, Organogenesis' Pivotal Trial defined "closure" as "full epithelialization of the wound with the absence of drainage." In contrast, Organogenesis' Retrospective Study defined "wound closure" as any wound less than $0.25cm^2$ at the last date included in the study period.

39. The statement that "Apligraf Closes More VLUs, Faster Compared to TheraSkin" also is demonstrably false and improperly compared to the results of Organogenesis' Pivotal Trial.

40. This statement fails to mention that Apligraf's closure rate is achieved through applying Apligraf at a much greater rate, as Table 3 of the Retrospective Study shows that Apligraf is used more often in shorter periods than TheraSkin.

41. Furthermore, the Advertisement links Organogenesis' Retrospective Study to Organogenesis' Pivotal Trial but fails to disclose the difference in how wound "closure" is defined, and falsely claims that the results in Organogenesis' Retrospective Study were based on wounds that had closed, when in fact, and according to Organogenesis' Retrospective Study, there is no evidence that they were fully epithelialized (i.e., closed) at the conclusion of the study.

42. The time in which a VLU closes is not a statement of subjective opinion but is capable of being systematically, reliably and scientifically measured.

43. In the Advertisement and linked article, Organogenesis claims that Apligraf closed more VLUs in a shorter period of time than TheraSkin. This statement constitutes a distinct establishment claim that the superiority of Apligraf over TheraSkin allegedly has been proven by competent and reliable scientific evidence.

44. But Apligraf does not, in fact, close more VLUs in faster time than TheraSkin, and Organogenesis' express claim that it does is false.

45. Organogenesis' Retrospective Study does not constitute competent and reliable scientific evidence that Apligraf closes more VLUs faster than TheraSkin and cannot support the conclusions attributed to it.

46. The use of the phrase "Comparative Effectiveness Study" in the Advertisement gives the consumer the false impression that it is a legitimate comparative effectiveness study,

which it is not, because Organogenesis' Retrospective Study fails to meet recognized standards for conduct of comparative effectiveness.

47. On information and belief, Organogenesis actions are willful and reflect intent to confuse consumers and profit from their deception.

FIRST CLAIM FOR RELIEF

(False Advertising under 15 U.S.C. § 1125(a))

48. Plaintiff incorporates by reference paragraphs 1 through 47 above as fully set forth herein.

49. Organogenesis has made and distributed in interstate commerce and in this District advertisements and related marketing materials that contain false and misleading statements of fact regarding its product, Apligraf. These advertisements contain actual false statements and/or misleading statements or failures to disclose, specifically the statements in the Advertisement including: 1) Apligraf Does it Again; 2) Similar to Apligraf's VLU pivotal trial; 3) Apligraf closes more VLUs, faster; and 4) certain statements in the linked Organogenesis Retrospective Study are materially false and/or misleading.

50. These statements actually deceive, or have a tendency to deceive, a substantial segment of customers and potential customers of wound care products. This deception is material in that it concerns inherent qualities or characteristics of Organogenesis' product and is likely to influence the purchasing decisions of Organogenesis' and Solsys' customers.

51. Organogenesis's false and misleading advertising statements and omissions injure both consumers and Plaintiff.

52. Organogenesis' false and misleading advertising statements and omissions violate Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a).

53. Organogenesis has caused, and will continue to cause, immediate and irreparable injury to Plaintiff, including injury to Plaintiff's wound care business, reputation and goodwill, for which there is no adequate remedy at law. Plaintiff is therefore entitled to an injunction under 15 U.S.C. § 1116 restraining Organogenesis, its agents, employees, representatives and all persons acting in concert with Organogenesis from engaging in future acts of false advertising and ordering removal of all of Organogenesis' false advertisements relating to Apligraf.

54. Pursuant to 15 U.S.C. § 1117, Plaintiff is further entitled to recover from Organogenesis the damages sustained by Plaintiff as a result of Organogenesis' acts in violation of 15 U.S.C. § 1125(a). Plaintiff is at present unable to ascertain the full extent of the monetary damages it has sustained by reason of Organogenesis' acts.

55. Pursuant to 15 U.S.C. § 1117, Plaintiff is further entitled to recover from Organogenesis the gains, profits and advantages that Organogenesis has obtained as a result of Organogenesis acts in violation of 15 U.S.C. § 1125(a). Plaintiff is at present unable to ascertain the full extent of the gains, profits and advantages Organogenesis has obtained by reason of Organogenesis' acts.

56. Pursuant to 15 U.S.C. § 1117, Plaintiff is further entitled to recover the costs of this action. Moreover, Plaintiff is informed and believes, and on that basis alleges, that Organogenesis' conduct was undertaken willfully and with the intention of causing confusion, mistake or deception, making this an exceptional case entitling Plaintiff to recover additional damages and reasonable attorneys' fees.

SECOND CLAIM FOR RELIEF

(False Advertising under Virginia Code §§ 18.2-216, 59.1-68.3)

57. Plaintiff incorporates by reference paragraphs 1 through 56 above as though fully set forth herein.

58. Organogenesis sells Apligraf to the public in competition with TheraSkin.

59. By falsely claiming that Apligraf closes more VLUs faster than TheraSkin, by comparing Organogenesis' Retrospective Study to Organogenesis' Pivotal Trial, and by causing to be disseminated Organogenesis' Retrospective Study despite its unreliability, Organogenesis has used false, deceptive and misleading representations in connection with the sale of its product Apligraf, in violation of § 18.2-216 the Virginia Code.

60. Organogenesis has published these false, deceptive and misleading statements in advertisements and related promotional materials and has widely disseminated these advertisements and promotional materials to the public via e-mail and other means of communication.

61. Plaintiff has been injured and is likely to be further damaged by these continuing violations of § 18.2-216.

62. Pursuant to § 59.1-68.3, Plaintiff is entitled to recover from Organogenesis the damages sustained by Plaintiff as a result of Organogenesis' acts in violation of section 18.2-216 of the Virginia Code. Plaintiff is at present unable to ascertain the full extent of the monetary damages it has sustained by reason of Organogenesis' acts.

63. Also pursuant to § 59.1-68.3, Plaintiff is entitled to recover reasonable attorneys' fees in connection with this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Organogenesis as follows:

1. For temporary, preliminary and permanent injunctive relief prohibiting Organogenesis, its agents, or anyone working for, in concert with or on behalf of Organogenesis from engaging in false or misleading advertising with respect to Apligraf and/or violating Section 43(a) of the Lanham Act and sections 18.2-216 and 59.1-68.3 of the Virginia Code, which relief includes but is not limited to removal of all false or misleading advertisements and corrective advertising to remedy the effects of Organogenesis' false advertising, including but not limited to the Advertisement;

2. For an order requiring Organogenesis to correct any erroneous impression persons may have derived concerning the nature, characteristics or qualities of Apligraf including without limitation the placement of corrective advertising and providing written notice to the public and a retraction of any references to or any information regarding Organogenesis' Retrospective Study;

3. Within ten (10) days from entry of an injunction, Organogenesis shall file a declaration with this Court signed under penalty of perjury certifying the manner in which Organogenesis has complied with the terms of the injunction;

4. That Organogenesis be adjudged to have violated 15 U.S.C. § 1125(a) by unfairly competing against Plaintiff by using false, deceptive or misleading statements of fact that misrepresent the nature, quality and characteristics of Apligraf;

5. That Organogenesis be adjudged to have violated Virginia Code § 18.2-216 by disseminating false, deceptive and misleading advertisements to the public for the purpose of selling Apligraf;

6. That Plaintiff be awarded damages that Plaintiff has sustained as a consequence of Organogenesis' conduct, and that such damages be trebled pursuant to 15 U.S.C. § 1117;

7. That Plaintiff be awarded profits obtain by Organogenesis as a consequence of Organogenesis' conduct;

8. That Plaintiff be awarded its cost and attorneys' fees;

9. That all of Organogenesis' misleading and deceptive materials be removed and destroyed pursuant to 15 U.S.C. § 1118;

10. That Plaintiff be granted prejudgment and post-judgment interest; and

11. That Plaintiff have such other and further relief as the Court deems just and proper.

Dated: March 16, 2018

EPSTEIN BECKER & GREEN, P.C.

/s/

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